2. 510(K) SUMMARY

K130602

This 510(k) Summary is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

APPLICANT	Biosense Webster, Inc. 3333 Diamond Canyon Road Diamond Bar, CA 91765
OFFICIAL CORRESPONDENT	John Jimenez Senior Specialist, Regulatory Affairs Telephone: 909-839-8534 Fax: 909-839-8804 Email: jjimene7@its.jnj.com
TRADE NAME	LASSO® NAV Duo Loop *eco* Catheter
COMMON NAME	Electrophysiological Mapping Catheter
CLASSIFICATION NAME	Electrode recording catheter or electrode recording probe
DEVICE CLASSIFICATION	Class II, 21 CFR §870.1220 Product Code: DRF
PRODUCT CODES	D-1354-01-S, D-1354-02-S, D-1354-03-S D-1354-04-S, D-1354-05-S, D-1354-06-S
PREDICATE DEVICE	Biosense Webster LASSO® 2515 NAV *eco* Variable Catheter (510(k) K113213)
REFERENCE DEVICE	Biosense Webster Webster® CS Catheter with EZ Steer Technology (510(k) K101345)

AUG 14 2013

SUBSTANTIALLY EQUIVALENT TO:

The Biosense Webster LASSO®NAV Duo Loop *eco* Catheter is substantially equivalent to the Biosense Webster LASSO® 2515 NAV *eco* Variable Catheter [510(k) K113213, cleared December 5, 2011] and the Biosense Webster Webster® CS Catheter with EZ Steer Technology [510(k) K101345, cleared May 13, 2010]. Like the predicate device, the LASSO®NAV Duo Loop *eco* Catheter features a tri-axial magnetic location sensor, allowing the ability to provide location information when used with the CARTO® 3 EP Navigation System, Version 3.2. The proposed catheter also has a similar circular loop of 20 electrodes at the distal tip of a 7 Fr diameter catheter, the same patient contact materials, and the same catheter connectivity as the predicate device. The original

intended use of the predicate device for diagnosis of heart arrhythmias remains the same in the proposed device; however, the proposed device will now have the added ability of deflecting in two directions (bi-directional). This latter capability is substantially equivalent to the Reference Device, the Webster® CS Catheter with EZ Steer Technology. The Webster® CS Catheter with EZ Steer Technology went through this same transition with FDA when FDA cleared the update of the uni-directional version to the bi-directional version.

DESCRIPTION OF THE DEVICE SUBJECT TO PREMARKET NOTIFICATION:

The LASSO®NAV Duo Loop *eco* Catheter has been designed to facilitate electrophysiological mapping of the atria of the heart with the CARTO® 3 EP Navigation System and a reference device. The catheter is deployed in the right or left atrium through an 8F guiding sheath. The bi-directional catheter consists of a circular spine on the distal tip, with platinum/iridium electrodes that can be used for stimulation and recording. The purpose of this Premarket Notification is to create a bi-directional fixed multi-loop high density circular diagnostic catheter for recording intracardiac signals and cardiac stimulation. The modifications consist of changing from a single variable loop to a fixed spiral loop, including an insertion tool with atraumatic tip to the catheter, and incorporating a bi-directional deflection (deflection in two directions) feature to the distal end of the catheter. The new catheter will retain the extended barrel ("pig tail") connector and will connect to the system cable by way of an accessory cable.

The LASSO® NAV Duo Loop eco Catheter features a fixed spiral loop design available in two diameters, 20mm diameter and 25mm diameter. Each catheter with 20 electrodes spaced along its multiple loops in a uni-polar configuration for the 20mm and either a uni-polar or bi-polar configuration for the 25mm.

The proposed catheters will continue to interface with standard recording equipment via interface cables and appropriate connectors.

INDICATIONS FOR USE:

The LASSO® NAV Duo Loop *eco* Catheter is indicated for multiple electrode electrophysiological mapping of the cardiac structures of the heart, i.e. recording or stimulation only. The catheter is designed to obtain electrograms in the atrial regions of the heart.

The LASSO® NAV Duo Loop *eco* Catheter provides location information when used with compatible CARTO® 3 EP Navigation Systems. (This catheter is not compatible with CARTO® 3 EP Navigation Systems prior to Version 3.2.)

TECHNICAL CHARACTERISTICS:

The LASSO® NAV Duo Loop *eco* Catheter is a typical electrophysiological catheter that is unique only in its geometrical arrangement of 20 ring electrodes spaced along its

multiple loops. Otherwise, there are no special technical aspects of the ability of this catheter to detect electrical signals from heart endocardium and transmit this information to the CARTO® 3 EP Navigation System and/or recording equipment for display, analysis, and interpretation in detection of various heart arrhythmias.

PERFORMANCE DATA:

The safety and performance of the LASSO® NAV Duo Loop *eco* Catheter have been validated through Bench Testing, Biocompatibility Testing, GLP Animal Study, and System Level Testing. Bench testing evaluated the integrity and performance of the LASSO® NAV Duo Loop *eco* Catheter following three times ethylene oxide (EtO) sterilization, thermal cycling, accelerated aging (equivalent to one year real-time aging), and simulated transportation conditions. After thorough investigations and mitigations where appropriate, the device passed all intended criteria in accordance with appropriate test criteria and standards. In addition, the proposed catheter was tested with the CARTO® 3 EP Navigation System to demonstrate compatibility. Based on the results of the risk analysis and the bench testing performed, it is concluded that the minor differences in design and use that exist between the predicate device and the LASSO® NAV Duo Loop *eco* Catheter do not compromise the safety and efficacy of the catheter. This testing demonstrates that the subject device is at least as safe and effective as the legally marketed predicate devices.

BASIS FOR DETERMINATION OF SUBSTANTIAL EQUIVALENCE:

The technological comparison and nonclinical studies demonstrate that the LASSO® NAV Duo Loop *eco* Catheter is safe and effective for anatomic mapping of the heart and establish equivalence to its predicate and reference devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

August 14, 2013

Biosense Webster, Inc.
C/O John Jimenez
3333 Diamond Canyon Rd
Diamond Bar, CA 91765 US

Re: K130602
Trade/Device Name: Lasso nav duo loop catheter
Regulation Number: 21 CFR 870.1220
Regulation Name: Electrode Recording Catheter
Regulatory Class: Class II
Product Code: DRF
Dated: July 1, 2013
Received: July 2, 2013

Dear John Jimenez:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Owen P. Faris -S

for Bram D. Zuckerman, Ph.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

1. INDICATIONS FOR USE STATEMENT

510(k) No (if known): _K130602_____

Device Name: LASSO® NAV Duo Loop *eco* Catheter

Indication for Use:

The LASSO® NAV Duo Loop *eco* Catheter is indicated for multiple electrode electrophysiological mapping of the cardiac structures of the heart, i.e. recording or stimulation only. The catheter is designed to obtain electrograms in the atrial regions of the heart.

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Prescription Use __X____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Digitally signed by Owen P. Faris -S
Date: 2013.08.14 08:30:52 -04'00'